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(71) Applicant(s)
Mathys Medizinaltechnik AG

(72) Inventor(s)
Walter Moser; Ulrich Wehrli

(74) Agent/Attorney
PHILLIPS ORMONDE and FITZPATRICK,367 Collins Street,MELBOURNE VIC 3000

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(71) Anmelder: MATHYS MEDIZINALTECHNIK AG [CH/CH]; Güterstrasse 5, CH-2544 Bettlach (CH).

(72) Erfinder: MOSER, Walter; Fliederweg 22, CH-3126 Kaufdorf (CH). WEHRLI, Ulrich; Gosseisstrasse 29, CH-3084 Wabern (CH).

(74) Anwalt: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

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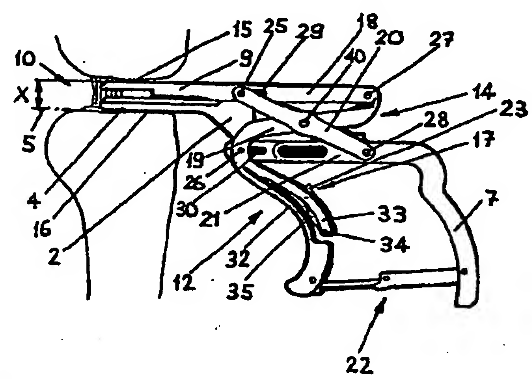

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(57) Abstract: The invention relates to a device for tensioning ligaments of non-spheroid joints in human or animal bodies, comprising A) a plate-shaped base body (2) with a right and a left blade (3; 4) whose contact surfaces (16) can be brought into contact with the surface of a first bone which is located on the side of the joint and lies adjacent to a joint (10) and a right and a left handle (6; 7); B) a right and a left tensioning lever (8; 9) whose contact surfaces (15) can be brought into contact with the surface of a second bone which is located on the side of the joint and lies adjacent to the joint (10); C) a right and a left operating lever (11; 12), each of which can be actuated simultaneously with the corresponding handle (6; 7) whilst holding the device, using the same hand; D) a right and a left parallel displacement device (13; 14) which can be used during a displacement of the operating levers (11; 12) to displace the contact surfaces (15) of the tensioning levers (6; 7) independently of one another in a perpendicular direction to the plane (5); E) the parallel displacement devices (13; 14) are quadruple-joint lever mechanisms, and F) a force indicator (17) displays the expansion force in newtons.

[Fortsetzung auf der nächsten Seite]

Ligament-tensioning device for non-spheroid joints

The invention concerns a device for the tensioning of ligaments on non-spherical joints in human or animal bodies.

Accordingly, the device according to the invention concerns a surgical instrument that allows the implantation of joint prostheses with a certain pretensioning of the ligaments and capsule structures controlling the joint.

A prerequisite for the good functioning of the joint provided with a prosthesis is a conflict-free interaction of the kinematics of the artificial joint and the soft parts surrounding the joint. In the case of non-spherical joints, e.g. knee joint or elbow joint, the movement of the joints is controlled by the surrounding capsule-ligament structures. In the case of a natural joint the geometry of the articulation surfaces and of the capsule-ligament apparatus are so harmonised that the physiological movement is possible. When replacing the diseased natural joint by an artificial joint, the harmonising of the kinematics of the artificial joint with the capsule-ligament apparatus is decisive as far as the mobility and stability of the joint provided are concerned. The natural structures of the capsules and the ligaments contain receptors to generate neurological signals to control the muscles of the extremities. These receptors convert mechanical stimuli, produced by the stretching of the surrounding tissue, into neurological signals. Depending on the fitted situation of the artificial joint, this information system gets damaged to a lesser or greater degree, and consequently the patient will suffer a loss of proprioceptivity of the extremity.

Those patients in whom during the implantation a good harmonisation of the soft part tensioning is achieved over the extent of the movement of the artificial joint, have a better proprioceptivity than those in whom the harmonisation was not as good (The Journal of Bone and Joint Surgery, Vol. 73-B, Jan. 1991 and Vol. 78-B, July 1996).

This information was established based on the replacement of knee joints and these modern surgical techniques are described, for example, in EP 0 322 363

WEHRLI and WO 96/17552 TODD. These surgical techniques are supported by an instrument, that allows to restore the statics of the leg to be operated with high accuracy and to securely and permanently anchor it on the skeleton. In addition to the restoring of a painless mobility, the alignment of the extremity with regard to the axis (varus/valgus) and the rotational positioning (internal/external rotation) is an important aim of the operation. Today's stand of instruments allows, on a large scale, the reproduction of correct relationship of the axes. The soft part situation, as a rule, is surgically adapted to suit the artificial joint, but the tensioning of the soft part structure, passively controlling the joint, is not quantified. A leading parameter of the surgical techniques described is the statically correct positioning of the artificial joint. After the statics has been restored, the soft part situation is corrected by so called capsule and ligament releases, while this correction is carried out in various bent positions of the joint.

Various authors have suggested instruments, the aim of which is a controlled dealing with the capsule-ligament structures during the implantation of an artificial joint. All these instruments have a spreading function using various technical solutions.

A spreading instrument for the tensioning of ligament structures in the knee during the implantation of a knee prosthesis is disclosed in US 5,649,929 CALLAWAY. The instrument is based on a scissors-like concept and allows the spreading of the knee joint when bent. On this occasion one arm of the instrument is resting on the proximal tibia, and the second arm is introduced centrally into the bent knee. The spreading movement can be locked by a spindle provided between the handles. The instrument is intended to be used exclusively for bent knees.

In EP 0 322 363 WEHRLI a ligament tensioning instrument is disclosed, that achieves a spreading effect also by means of two scissors-like levers, that can be locked with a spindle and nut provided between the handles. The instrument rests on the tibia on the bone screw introduced below the joint surface and is introduced in the centre of the bent knee and then spread out. In the same patent an instrument is described for the tensioning of the ligaments with extended knee,

that drives two spreaders guided in a longitudinal guide by means of two threaded spindles. The two spreaders, which can be separately operated, make a separate spreading of the two compartments of the knee joint possible. In contract to the above described one, this double-spreader produces a parallel spreading movement. This produces a spreading movement that does not result in the angular change of the spreader at various spreading paths, as this is the case for the scissors-type one.

In WO 96/17552 TODD a ligament tensioner for the implantation of knee prostheses is disclosed, that has two separate spreaders, which are also guided in a longitudinal guide. The operation is carried out by means of two hand levers, while the spread position can be locked by ratchet mechanism.

When compared with spreaders operating with threaded spindles, hand lever-operated spreaders have the advantage that the surgeon has a direct control of the spreading force via the manual force. Depending on the lever ratios the conversion of the manual force into spreading force can be freely chosen, similarly to surgical pliers and scissors. The knowledge and training of a surgeon guarantee the reliable handling of such instruments. The manual intuitive control of the spreading force via a threaded spindle is clearly less accurate and may lead to an overstraining of the soft parts.

It is a disadvantage of the aforementioned spreading instruments that in addition to the intuitive control no quantification of the force, with which the soft parts are tensioned, is possible by the instrument.

Furthermore, from US 4,997,432 a spreading instrument with a four-bar level mechanism is known, that, admittedly, does not allow a quantifying of the force used. Finally, from US 4,899,761 a device is known, wherein the force applied can be measured by means of electronic strain gauges.

The above discussion of background art is included to explain the context of the invention. It is not to be taken as an admission or suggestion that any of the documents or other material referred to was published, known or part of the

common general knowledge in Australia at the priority date of any one of the claims of this specification.

Broadly, the present invention provides a device for the tensioning of ligaments on non-sperical joints in human or animal bodies including:

a prism-shaped, cylindrical or plate-shaped base body with a right blade and a left blade each having a blade contact surface in one plane and consequently can be brought into contact parallel with the surface of a first bone of a non-spherical joint on the side of the joint, as well as a right handle and a left handle;

a right tensioning lever and a left tensioning lever with each having a lever contact surface that are arranged parallel to the blade contact surfaces, while between the respective contact surfaces of the right tensioning lever and of the right blade a tensioning width Y, and between the respective contact surfaces of the left tensioning lever and of the left blade the same or another tensioning width X, can be adjusted, and the lever contact surfaces can be brought into contact with the surface on the joint side of a second bone adjacent to the joint;

a right operating lever and a left operating lever that can be actuated while simultaneously holding the device individually with one hand each on the corresponding handle and can be actuated with the same hand; and

a right parallel displacing device and left parallel displacing device, that can be operated by the corresponding operating lever and are so connected with a tensioning lever each, that when the operating lever is moved the tightening widths X and Y, respectively, can be adjusted independently from one another, wherein the parallel displacing devices are four-bar lever mechanisms, and each operating lever includes a force indicator.

Advantageously the device of the invention is able to tension the capsule-ligament structures of a joint to be provided with a parallel spreading movement, while making a manual control and additionally a simultaneous quantitative control of the spreading force possible. The instrument is also able to be used both in bent and extended joints. For this purpose two separate spreaders are used, that are operated by means of two pairs of handles and the two four-bar mechanisms are spread parallel. To

quantify the force per spreader a leaf spring element is used that indicates the spreading force in Newtons via an indicator and a graduated scale.

Thus, the device according to the invention comprises a prism-shaped, cylindrical or plate-shaped base body and two blades connected with the base body and symmetrical to an anterior-posterior extending plane, which blades can be brought to rest parallel on the flat osteotomised surface on the side of the joint of a first bone adjacent to a non-sperical joint, a left and right handle, a left and right operating lever which simultaneously with the holding of the device with one hand each can be actuated by the same hand on the corresponding handle, and a left and a right tensioning lever which with their contact surfaces can be brought to rest on the surface on the side of the joint of a second bone adjacent to the joint. The movement of the tensioning lever relative to the blades is carried out by a left and right parallel displacing device, that can be operated by means of the corresponding operating lever and are so connected with a tensioning lever each, that during the movement of the operating lever the contact surfaces of the tensioning levers can be moved independently from one another parallel to the contact surfaces on the blades. The parallel displacing devices are constructed as four-bar lever mechanisms. The magnitude of the spreading force between the contact surfaces on the claws and the contact surfaces on the tensioning levers can be read off on a graduated force meter, while during the tensioning of the ligaments by actuating the device a separate reading off of the force exerted on the left and on the right operating levers is possible. The position of the tensioning lever relative the blades can be detachably locked by means of locking elements.

In a preferred embodiment of the device according to the invention the force indicator has a moving indicator lever, the edges of which move relative to the

scale. This indicator lever is moved by the longitudinal bending of an operating lever part that can be bent relative to the other fork-like provided operating lever part by a manually applied tensioning force that is not subjected to this tensioning force. If by means of the tensioning force both operating lever parts are moved relative one another, the indicator lever moves relative to the graduated scale.

The parallel displacing devices, constructed as four-bar lever mechanisms, preferably comprise four levers, while an upper lever and a lower lever are provided parallel, the upper lever is connected with the corresponding tensioning lever, the lower lever is connected with the base body and the connecting levers form the scissors bars, so that the upper lever and the lower lever can move parallel towards or away from one another.

The lengths of the levers are so chosen, that with regard to the force transfer between the tensioning force exerted with the respective hand between the corresponding operating lever and handles and the distractive force exerted on the bones adjacent to the joint by the corresponding tensioning lever and the corresponding blade within a tensioning width between the blade contact surfaces of the blades and the lever contact surfaces of the tensioning levers between 5 mm and 35 mm, preferably between 7 mm and 25 mm, the parallel displacing devices ensure a transmission ratio of 1:1.

The advantages achieved by the invention are essentially that by virtue of using the ligament tensioner according to the invention the tensioning forces exerted on the ligament during the tensioning of the ligaments can be intuitively controlled by the forces applied by hand to the operating elements and the transmission ratio of 1:1 on the one hand, and on the other by simultaneously indicating the force a quantitative control can be carried out. This quantitative indication of the force ensures that the medial and the lateral ligaments, which are separately tensioned by the tensioning force applied by the left or the right hand, can be acted upon with the same pretensioning force or with deliberately different pretensioning forces.

The invention to be used in a human knee joint is explained in detail in the following based on the partly schematical illustrations.

They show in:

Fig.1 - a side view of the preferred embodiment of the device according to the invention,

Fig.2 - a top view of the embodiment of the device according to the invention, illustrated in Fig.1,

Fig.3 - a perspective illustration of the embodiment of he device according to the invention, illustrated in Figs.1 and 2, used in a bent knee joint, and

Fig.4 - a perspective illustration of the embodiment of he device according to the invention, illustrated in Figs.1 and 2, used in a straight knee joint.

Figs.1 and 2 illustrate the device 1 according to the invention with a spreading mechanism and its locking. The device comprises a plate-shaped base body 2, that for the purpose of a reliable introduction of the spreading force into the tibia has a left blade 4 and a right blade 3 with blade contact surfaces 16 lying in one plane 5. A left handle 7 and a right handle 6 are provided on the base body 2, opposing the blades 3, 4, respectively, which handles enable the holding of the device with two hands. The device also has, corresponding to the arrangement of the blades 3, 4 and above the blades 3, 4, a left tensioning lever 9 and a right tensioning lever 8, which rest with their lever contact surfaces 15 on the opposite situated part of the joint 10. The spreading action is produced by actuating the right handle 6 together with the right operating lever 11 for the medial or lateral part of one joint. By actuating the left handle 7 together with the left operating lever 12 the spreading function is produced on the other, depending on the joint, medial or lateral part of the joint. A left parallel displacing device 14 has a right parallel displacing device 13 allow a parallel displacement of both pairs of spreaders relative to the blade contact surfaces 16 and the lever contact surfaces 15. The parallel displacing devices 13, 14 are executed as four-bar mechanisms in the form of

intersecting bars and each comprise four levers 18, 19, 20, 21, wherein the levers 18 on the side of the tensioning lever and the levers 21 on the side of the base body are provided parallel, whereas the two levers 19, 20 intersect. The four levers 18, 19, 20, 21 are joined with one another by means of five spindles 25, 26, 27, 28, 40. Two of the spindles 25, 26 are displaceably mounted in the parallel levers 18, 21 in slots 29, 30 running parallel to the contact surfaces 25,26. This construction of the parallel displacing devices 13, 14 allows that the lever 18 on the side of the tensioning lever and the lever 21 on the side of the base body can move parallel towards or away from one another. The lengths of the levers 18, 19, 20, 21 are so chosen, that when the tensioning width X between the blade contact surfaces 16 on the blades 3, 4 and the lever contact surfaces 15 on the tensioning levers 8, 9 is between 5 mm and 25 mm, the transmission ratio between the manually exerted tensioning forces acting on the handles 6, 7 and the operating levers 11, 12 and the distractive forces exerted on the bones adjacent to the joint 10 (Figs. 3 and 4) is 1:1.

Between the handles 6, 7 and the operating levers 11, 12 a locking element 22 each is provided, that can be locked in any position of the operating levers 11, 12 relative to the handles 6, 7. These locking elements 22 act like a sort of a ratchet mechanism that can be pushed together during the spreading and locks when the spread position is achieved. A hand lever 31 is used for the release of the locked position.

The magnitude of the spreading force can be read off on a force meter 17 with a graduated scale 24 and a displaceable indicator lever 23. This indicator lever 23 is moved by the longitudinal bending of an operating lever part 32 that can be bent by a manually applied tensioning force relative to the other fork-like provided operating lever part 33 that is not subjected to this tensioning force. The indicator lever 23 is mounted by means of a pivot spindle 34 in the operating lever part 33 not subjected to the tensioning force and with a cam 35 abuts against the operating lever part 32 subjected to the tensioning force. When the two operating lever parts 32, 33 are moved relative one another by means of the tensioning force, the indicator lever 23 rotates about the pivot spindle 34 and the manually

exerted tensioning force is indicated by the indicator lev[illegible] on the graduated scale 24.

For the control of the axial relationships in the joint to be cared for, guide bars (not illustrated) can be inserted into a guide 36, that is joined, angularly fixed, with the base body 2.

For the use in a bent joint 10 (Fig.3) a deliberately different stability of the two parts of the joint can be produced by spreading the medial and lateral joint parts to a different extent, thus achieving a rotational mobility, like the one desired, for example, for the bent knee joint. This different stability can be produced by specified different medial and lateral spreading forces.

When used for a straight joint (Fig.4), the stability of the joint can be accurately adjusted in an exactly specified extended position, e.g. with slight hyperextension, as this is desirable, for example, for the knee joint.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for the tensioning of ligaments on non-sperical joints in human or animal bodies including:

a prism-shaped, cylindrical or plate-shaped base body with a right blade and a left blade each having a blade contact surface in one plane and consequently can be brought into contact parallel with the surface of a first bone of a non-spherical joint on the side of the joint, as well as a right handle and a left handle;

a right tensioning lever and a left tensioning lever with each having a lever contact surface that are arranged parallel to the blade contact surfaces, while between the respective contact surfaces of the right tensioning lever and of the right blade a tensioning width Y, and between the respective contact surfaces of the left tensioning lever and of the left blade the same or another tensioning width X, can be adjusted, and the lever contact surfaces can be brought into contact with the surface on the joint side of a second bone adjacent to the joint;

a right operating lever and a left operating lever that can be actuated while simultaneously holding the device individually with one hand each on the corresponding handle and can be actuated with the same hand; and

a right parallel displacing device and left parallel displacing device, that can be operated by the corresponding operating lever and are so connected with a tensioning lever each, that when the operating lever is moved the tightening widths X and Y, respectively, can be adjusted independently from one another, wherein the parallel displacing devices are four-bar lever mechanisms, and each operating lever includes a force indicator.

2. A device according to claim 1, wherein during the tensioning of the ligaments the force indicators make a separate reading of the force exerted on each operating lever possible.

3. A device according to claim 1 or 2, wherein the parallel displacing devices are made up from lever mechanisms, each of them comprising four levers, wherein one upper lever and a lower lever are provided parallel, the

upper lever is connected with the respective tensioning lever, the lower lever is connected with the base body and the connecting levers form the scissors bars, so that the upper lever and the lower lever can move parallel towards or away from one another.

4. A device according to any one of claims 1 to 3, wherein with regard to the force transfer between the tensioning force exerted on the respective operating lever with the fingers of the respective hand and the distractive force exerted on the bone adjacent to the joint by the respective tensioning lever and the corresponding blade, the parallel displacing devices ensure a transmission ratio of 1:1 with a defined working range.

5. A device according to claim 4, wherein the possible working range consists in that the tensioning widths X and Y, respectively, between the blade contact surfaces on the blades and the lever contact surfaces on the tensioning levers are between 5 mm and 35 mm.

6. A device according to claim 5, wherein the defined working range consists in that the tensioning widths X and Y between the blade contact surfaces on the blades and the lever contact surfaces on the tensioning levers, respectively, are between 7 mm and 12 mm.

7. A device according to any one of claims 1 to 6, wherein the operating levers are longitudinally elastically flexible.

8. A device according to any one of claims 1 to 7, wherein between a handle and the corresponding operating lever telescope-type locking elements that can be blocked in their lengths, are provided, by means of which the distance between the blade contact surface of a blade and the lever contact surface of the corresponding tensioning lever can be detachably fixed.

9. A device according to any one of claims 2 to 8, wherein the force indicator includes an indicator lever that can be displaced relative a graduated scale.

10. A device according to claim 9, wherein the indicator lever can be actuated by the outward bending of the corresponding operating lever.

11. A device for tensioning of ligaments on non-sperical joints in human or animal bodies substantially as herein described with reference to the accompanying drawings.

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PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
MATHYS MEDIZINALTECHNIK AG

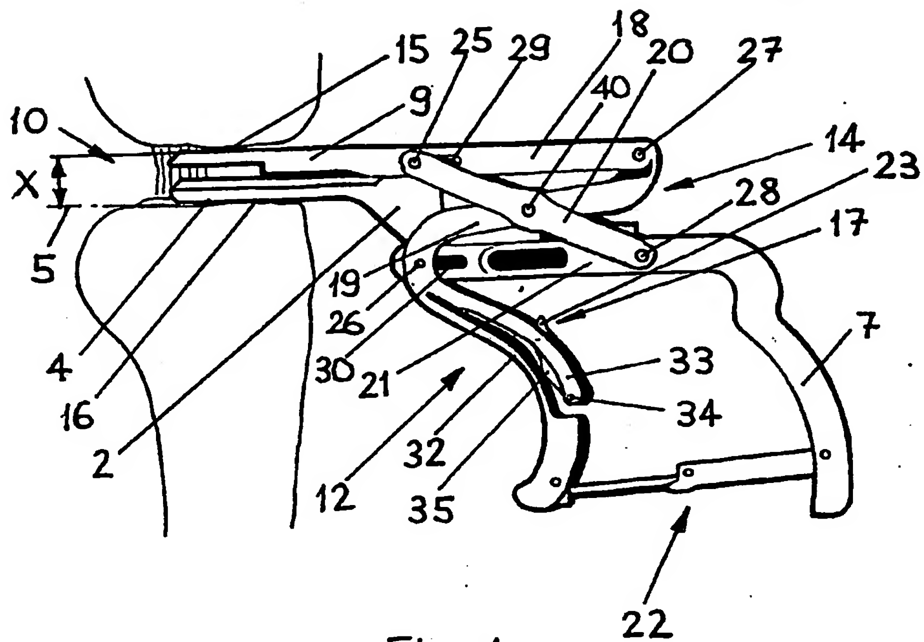
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Fig. 1

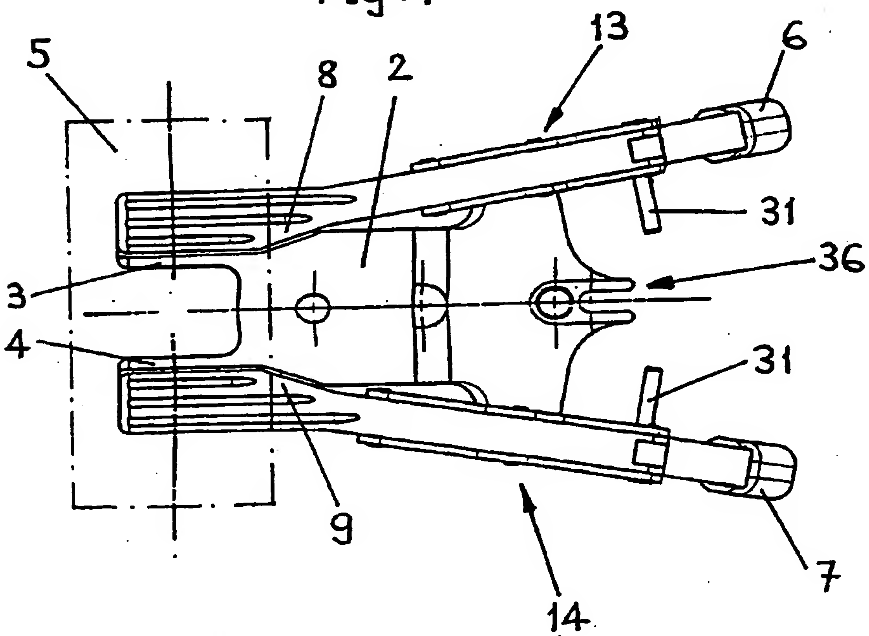
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Fig. 2

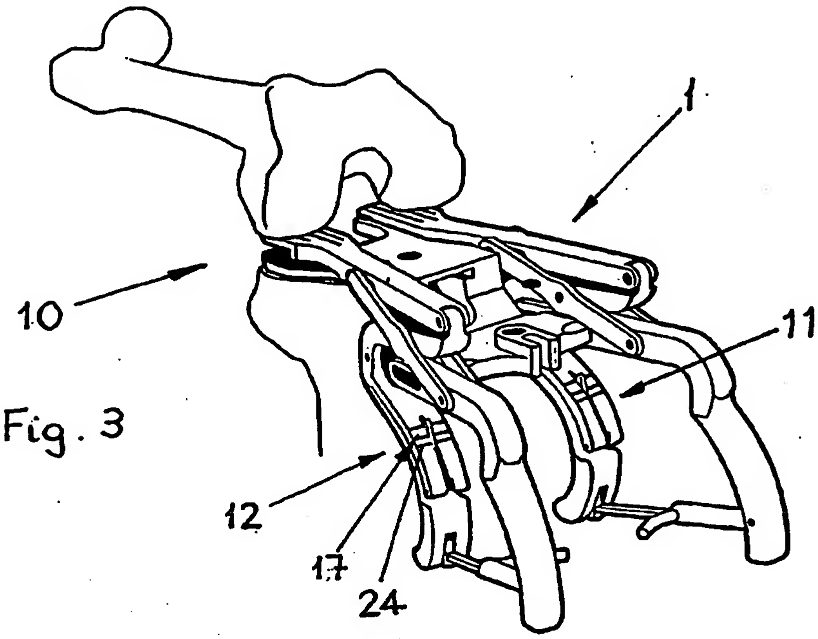

Fig. 3

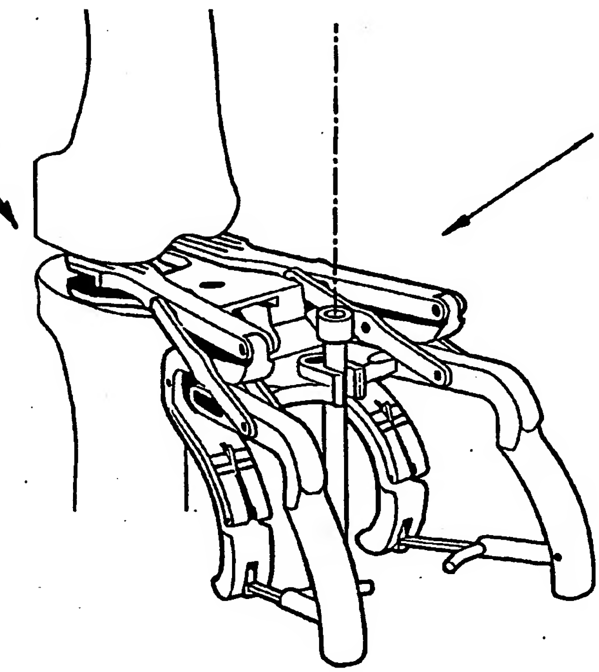

Fig. 4